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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/642,557	08/18/2000	Brydon L. Bennett	10624-046-999	6892
20583	7590	04/11/2005	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			STOCKTON, LAURA	
			ART UNIT	PAPER NUMBER
			1626	
DATE MAILED: 04/11/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/642,557

Applicant(s)

BENNETT ET AL.

Examiner

Laura L. Stockton, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 January 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 24-35, 38 and 40-54 is/are pending in the application.
- 4a) Of the above claim(s) 28-33 and 40-46 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 2, 4-8, 25, 34, 35, 38, 51 and 53 is/are allowed.
- 6) ☒ Claim(s) 3, 24, 26, 27, 52 and 54 is/are rejected.
- 7) ☒ Claim(s) 47-50 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION**

Claims 1-8, 24-35, 38 and 40-54 are pending in the application.

***Election/Restrictions***

During a telephone conversation with Mr. Michael Bruner on July 6, 2004, a provisional election was made with traverse to prosecute the invention of Group I (drawn to products).

The requirement is still deemed proper and is therefore made FINAL.

Claims 28-33 and 40-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

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Rejections made in the previous Office Action that do not appear below have been overcome. Therefore, arguments pertaining to these rejections will not be addressed.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

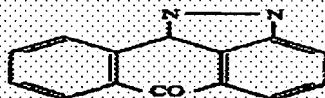
A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Tzikas {U.S. Pat. 4,202,827}.

Tzikas disclose Example 12 in water (column 4).

volume of water. The suspension is then poured into a mixture of ice and water and filtered. The filter cake is washed neutral with water and dried, affording 22.2 parts of pyrazolanthrone of the formula.



(4)

***Response to Arguments***

Applicants' arguments filed January 4, 2005 have been fully considered. Applicants argue that Tzikas does not disclose any pharmaceutical compositions, let alone a pharmaceutical composition comprising a compound encompassed by the pharmaceutical composition of instant claim 24.

Applicants' arguments have been considered but have not been found persuasive. Instant claim 24 is directed to a pharmaceutical composition comprising a compound and a pharmaceutically acceptable carrier. Tzikas disclose Example 12 in water (column 4, lines 42-54). It is known in the pharmaceutical art that water is useful as a liquid carrier in pharmaceutical compositions. See, for example, column 39, lines 62-64 in Showalter et al. {U.S. Pat. 4,556,654}. Further, in the instant specification on page 23, lines 2-3, water is listed as an acceptable liquid carrier. Therefore, the rejection is proper and is maintained.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 26, 27, 52 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Showalter et al. {U.S. Pat. 4,556,654}.

***Determination of the scope and content of the prior art (MPEP***

***§2141.01)***

Applicants claim pyrazoloanthrone compounds. Showalter et al. (column 1; column 21, lines 38-62; column 35, lines 64-68; columns 39-42; and especially the 1<sup>st</sup>, 6<sup>th</sup> and 8<sup>th</sup> compounds in columns 25-26) teach pyrazoloathrone compounds that are structurally similar to the instant claimed compounds.

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*Ascertainment of the difference between the prior art and the claims*

*(MPEP §2141.02)*

The difference between the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

*Finding of prima facie obviousness--rational and motivation (MPEP*

*§2142-2413)*

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., an anti-tumor agent).

One skilled in the art would thus be motivated to prepare compounds embraced by the prior art to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial compounds which would be useful, for example, in treating tumors. The

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instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

### ***Response to Arguments***

Applicants' arguments filed January 4, 2005 have been fully considered. Applicants state that to establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the cited reference or generally known to one of ordinary skill in the art, to modify the reference to arrive at the claimed compounds and there must also be reasonable expectation of success.

Applicants argue that although Showalter et al. teach unsubstituted and substituted N-2 position compounds, Showalter et al. teach an overwhelming majority of individual compounds that are substituted at the N-2 position. In response, it is well



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established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to person of ordinary skill in the art. In re Boe, 148 USPQ 507, 510 (CCPA 1966).

Applicants argue that the instant claimed compounds are unsubstituted at the N-2 position and are useful in treating certain diseases, including but not limited to cancer. In response, there is no requirement that the prior art must suggest that the claimed product will have the same or similar utility as that discovered by applicant in order to support a legal conclusion of obviousness. In re Dillon, 16 U.S.P.Q. 2d 1897, 1904 (Fed. Cir. 1990).

Applicants argue that it is well established that the fact that a claimed compound may be encompassed by a disclosed generic formula does not itself render that compound obvious. In re Jones, 958 F.2d 347, 350 (Fed.

Cir. 1992) Applicants further argue that the instant compounds are not obvious in view of the disclosure of Showalter et al. and that the disclosure of Showalter et al. leads one way from the instant claimed compounds. In response, Showalter et al. teach that the compounds of the formula in column 1, lines 18-64 have utility such as an anti-tumor, anti-microbial, anti-bacterial and anti-fungal agent. This utility embraces compounds that are unsubstituted or substituted at the N-2 position. As stated above, consideration of a reference is not limited to the preferred embodiments or working examples. However, Showalter et al. do prepare an unsubstituted N-2 position species in column 25, the sixth compound in the table.

Applicants argue that the various data (columns 28-35) in Showalter et al. teach that the compounds which are substituted at the N-2 position have better activity than the compound which is unsubstituted at

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the N-2 position. In response, the data in columns 25 and 26 have been considered. The data in columns 25-26 show that the unsubstituted N-2 position compound (listed compound 6) has a better activity (column 23, lines 39-52) than some substituted N-2 compounds (listed compounds 7, 8, 9, etc.).

Additionally, the data in columns 37 and 38 have been considered. The data in columns 37 and 38 show that there are some N-2 substituted compounds that have about the same, or less, activity (listed compounds 3, 16, 29 and 32) than the N-2 unsubstituted compound (listed compound 4). The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

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***Allowable Subject Matter***

Claims 47-50 are objected to as being dependent upon a rejected base claim.

Claims 1, 2, 4-8, 25, 34, 35, 38, 51 and 53 are allowed over the art of record.

***Conclusion***

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened

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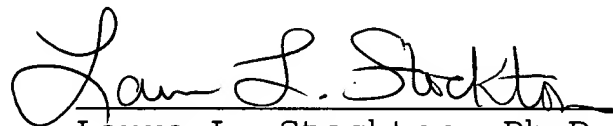
statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in cursive script, reading "Laura L. Stockton", written over a horizontal line.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

April 6, 2005